OCT - 4 2006

Section 5 - 510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Submitter

Haemonetics Corporation
400 Wood Road
Braintree, MA. 02184-9114

Contact

Gabriel J. Muraca, Jr.
RA Project Manager
Haemonetics Corporation
355 Wood Rd.
Braintree, MA. 02184-9114
T: 781-356-9553
F: 781-356-9974
Email: gmuraca@haemonetics.com

Device Name

Proprietary Name:	Haemonetics® SmartSuction Solo™
Common Name:	AC Powered Suction Device
Classification Name:	AC Powered Suction Pump

Predicate Device

The predicate device is the SmartSuction HARMONY™ device, cleared under K052626 in October 2005.

Description

Powered suction pumps are described in FDA regulation, 21 CFR 878.4780, as:

"A powered suction pump is an AC-powered device intended to be used to remove infectious materials from wounds or fluids from patient's airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter. The FDA classified the device as a class II medical device".

Haemonetics® SmartSuction Solo™ (HSS) is a product line extension from the SmartSuction HARMONY™ device, which was cleared by FDA under K052626 in October 2005. The SmartSuction Solo device is an AC-powered, stand-alone device designed to be used as a suction source to replace wall suction in the operating room to remove fluids and debris from the surgical field during surgical procedures. The SmartSuction Solo device is intended for use by trained personnel under the direction of the physician. The attending physician is responsible for the proper use of these devices. Therefore, both these devices are to be used as a prescription medical device, which is indicated in the labeling as "Rx only".

Indications for Use:

The SmartSuction Solo device is an AC-powered, stand-alone device designed to be used as a suction source to replace wall suction in the operating room to remove fluids and debris from the surgical field during surgical procedures.

The SmartSuction Solo device is not intended for endotracheal suction. The SmartSuction Solo device automatically adjusts suction up to 150 mmHg negative pressure when the suction tip is occluded. Do not use the SmartSuction Solo device as a suction source for a procedure where 150 mmHg of suction could damage underlying tissue.

Both devices are intended for use by trained operating room personnel under the direction of a physician. The attending physician is responsible for the proper use of these devices. Therefore, both these devices are to be used as a prescription medical device, which is indicated in the labeling as "Rx only".

Performance Testing – Bench

Haemonetics has conducted testing to verify the electrical safety and performance characteristics as described in the Operation Manual. A detailed list of testing is provided with test protocols and reports.

Substantial Equivalence

The substantial equivalence of the SmartSuction Solo is supported by its similarities in intended use, technological characteristics, and performance as compared to the currently marketed SmartSuction HARMONY device. Both devices have the same technological characteristics. They are similar in design and materials of construction. Both electromechanical devices are the same and consist of a vacuum pump and control circuitry. Verification and validation testing has been completed on the SmartSuction Solo and provide valid scientific evidence to demonstrate the devices are functionally equivalent.

Date: August 17, 2006

Gabriel J. Muraca, Jr.
Regulatory Affairs Project Manager
Haemonetics Corporation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 4 2006

Haemonetics Corporation
% Mr. Tamas Borsai
TUV Rheinland of North America, Inc.
12 Commerce Road
Newton, Connecticut 06470

Re: K062801
Trade/Device Name: Haemonetics® SmartSuction Solo™
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction cup
Regulatory Class: Class II
Product Code: BTA
Dated: September 18, 2006
Received: September 19, 2006

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use Statement

Indications for Use:

510(k) Number (if known): K062801

Device Name:

Haemonetics® SmartSuction Solo™

The SmartSuction Solo device is an AC-powered, stand-alone device designed to be used as a suction source to replace wall suction in the operating room to remove fluids and debris from the surgical field during surgical procedures. The SmartSuction Solo device is intended for use by trained personnel under the direction of the physician.

The SmartSuction Solo device is not intended for endotracheal suction. The SmartSuction Solo device automatically adjusts suction up to 150 mmHg negative pressure when the suction tip is occluded. Do not use SmartSuction Solo device as a suction source in any procedure where 150 mmHg of suction could damage underlying tissue.

This device is intended for use by trained personnel under the direction of a physician. The attending physician is responsible for the proper use of these devices. Therefore, the device is to be used as a prescription medical device, which is indicated in the labeling as "Rx only".

Prescription Use __X__ and/or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices